

**REMARKS**

**I. Claims**

Claims 1 and 4-47 are currently pending. Claims 1 and 4-47 stand rejected. Claims 1 and 46 are now amended. Reconsideration of the above-identified application in view of the amendments to claims 1 and 46 and the following remarks is respectfully requested.

**1. Rejection of Claim 1 Under 35 U.S.C. §112**

Claim 1 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action asserts that claim 1 is indefinite because it is unclear whether the limitation “that is engageable with said first mounting member to guide movement of said first retaining member into position between the first and second vertebrae” is modifying the guide or the outer surface of the guide. Claim 1 is now amended in a manner believed to overcome this rejection. Reconsideration of this rejection of claim 1 is respectfully requested.

**2. Rejection of Claim 46 Under 35 U.S.C. §101**

Claim 46 has been rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Specifically, the Office Action asserts that claim 46 positively recites a human by stating that the “first mounting member extends out of the first vertebra.” Claim 46 is now amended in a manner believed to overcome this rejection. Reconsideration of this rejection of claim 46 is respectfully requested.

**3. Rejection of Claims 1, 4, 7, 8, 12, 13, 16-22, 25, 26, 30, 32-34, and 41-47 Under 35 U.S.C. §102(e)**

Claims 1, 4, 7, 8, 12, 13, 16-22, 25, 26, 30, 32-34, and 41-47 have been rejected as anticipated under 35 U.S.C. §102(e) by U.S. Patent Application Publication US 2003/0187506 to Ross et al (hereinafter, "Ross"). It is respectfully submitted that claim 1 and claims 4, 7, 8, 12, 13, 16-22, 25, 26, 30, 32-34, and 41-47 are novel over Ross.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Foundation v. Genentech Inc., 1927 F.2d 1565, 8 USPQ2d 1001 (Fed. Cir. 1991).

Claim 1 recites an apparatus for replacing a damaged spinal disc in a spinal column. The apparatus comprises an artificial disc that includes a resilient core having a first surface and a second surface. A first retaining member is connected to the first surface of the resilient core. A second retaining member is connected to the second surface of the resilient core. The first retaining member has an outer surface engageable with a first vertebra of the spinal column and an inner surface facing the first surface of the resilient core. The second retaining member has an outer surface engageable with a second vertebra of the spinal column and an inner surface facing the second surface of the resilient core. The outer surfaces of the first and second

retaining members face away from each other. The apparatus also comprises a first mounting member that is connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae. The first mounting member is engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. The first retaining member includes a guide with an outer surface that extends outwardly from the outer surface of the first retaining member. The outer surface of the guide is also engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae.

This rejection under 35 U.S.C. §102(e) based on Ross appears to be based specifically on Fig. 3B of Ross, as the Office Action includes a second rejection under 35 U.S.C. §102(e) based on Ross that appears to be based specifically on Fig. 5 of Ross. The Office Action states, with particular reference to Fig. 3B of Ross, that Ross discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Ross comprises an artificial disc that includes (a) a resilient core (member 20 of Ross) having a first surface and a second surface, (b) a first retaining member (member 22 of Ross), and (c) a second retaining member (member 24 of Ross). The Office Action also states that the first retaining member of Ross has an inner surface facing the resilient core and an outer surface engageable with a first vertebra of the spinal column. Further, according to the Office Action, the second retaining member of Ross has an inner surface facing the resilient core and an outer surface engageable with a second

vertebra of the spinal column. Still further, the Office Action asserts that the apparatus of Ross also comprises a first mounting member (member 14 of Ross) that is (i) connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. Lastly, according to the Office Action, the first retaining member of Ross includes a guide (dovetail 30a of Ross) with an outer surface that (i) extends outwardly from the outer surface of the first retaining member and (ii) is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae.

It is respectfully submitted that Ross does not anticipate the apparatus of claim 1 in that each and every element recited in claim 1 is not disclosed by Ross as required by 35 U.S.C. §102(e). Specifically, claim 1 recites an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of the spinal column and a second retaining member having an outer surface engageable with a second vertebra of the spinal column. Claim 1 also recites a first mounting member that is (i) connectable with the first vertebra and the artificial disc and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae. The Office Action asserts that members 22 and 24 of Ross correspond to the first and second retaining members, respectively, of claim 1. As recognized in the Office Action, however, Ross does not disclose that either

member 22 or member 24 has an outer surface engageable with a vertebra of a spinal column. The Office Action attempts to overcome this deficiency of Ross by making the unsupported assertions, as to members 22 and 24, respectively, of Ross, that "if one so desired, one could engage the outer surface with a first vertebra" and "if one so desired, one could engage the outer surface with a second vertebra."

Beyond the absence of any disclosure in Ross to support the foregoing assertions, the Office Action states that the member 14 of Ross corresponds to the first mounting member of claim 1. According to the Office Action, the member 14 of Ross is (i) connectable with a first vertebra and the artificial disc to position the artificial disc between first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. It is respectfully submitted that if the member 14 of Ross is engageable with the artificial disc to guide movement of the artificial disc into position between the first and second vertebrae, there is no possibility of the member 22 of Ross engaging a vertebra. Specifically, if the members 22 and 24 are already engaged with vertebrae, the member 22 cannot be guided into position between the vertebrae by the member 14 of Ross. If, on the other hand, the member 14 of Ross is engageable with the member 22 of Ross after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae, as would be required by claim 1, the member 14 of Ross would fully cover the outer surface of the member 22 of Ross (and a similar member 16 would fully cover the outer surface of member 24 of Ross). Thus, there would be no possibility of the outer surface of the member 22 of Ross (or

the member 24) being engaged with a vertebra after the artificial disc is in position between the first and second vertebrae.

Since Ross does not disclose an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of the spinal column, as recited in claim 1, Ross cannot anticipate claim 1 under 35 U.S.C. §102(e). Amended claim 1 is therefore novel and allowable over Ross.

Claims 4, 7, 8, 12, 13, 16-22, 25, 26, 30, 32-34, and 41-47 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the foregoing discussion of claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 4, 7, 8, 12, 13, 16-22, 25, 26, 30, 32-34, and 41-47 define over Ross, and withdrawal of this rejection of claims 4, 7, 8, 12, 13, 16-22, 25, 26, 30, 32-34, and 41-47 is respectfully requested.

**4. Rejection of Claims 1, 9-11, 14, and 15 Under 35 U.S.C. §102(b)**

Claims 1, 9-11, 14, and 15 have been rejected as anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,893,889 to Harrington (hereinafter, "Harrington"). It is respectfully submitted that claim 1 and claims 9-11, 14, and 15 are novel over Harrington.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the

invention.” Scripps Clinic & Research Foundation v. Genentech Inc., 1927 F.2d 1565, 8 USPQ2d 1001 (Fed. Cir. 1991).

The Office Action states that Harrington discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Harrington comprises an artificial disc that includes (a) a resilient core (member 68 of Harrington) having a first surface and a second surface, (b) a first retaining member (member 54 of Harrington), and (c) a second retaining member (member 34 of Harrington). The Office Action also states that the first retaining member of Harrington has an inner surface facing the resilient core and an outer surface engageable with a first vertebra of the spinal column. Further, according to the Office Action, the second retaining member of Harrington has an inner surface facing the resilient core and an outer surface engageable with a second vertebra of the spinal column. Still further, the Office Action asserts that the apparatus of Harrington also comprises a first mounting member (member 32 of Harrington) that is (i) connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae.

In addition to the foregoing, the Office Action hypothesizes that the apparatus of Harrington could be inserted between two vertebrae in pieces and then, presumably, assembled. In this hypothetical assembly, according to the Office Action, because the member 32 of Harrington has pins 38, it could be attached to a vertebra independently of screws 64 and 66. The Office Action states that the first

retaining member of Harrington (member 54 of Harrington) includes a guide (threads of hole 55 of Harrington) with an outer surface that extends outwardly from the outer surface of the first retaining member and that is engageable with the first mounting member to guide movement of the first retaining member into position between first and second vertebrae. According to the Office Action, if one so desired, one could place the guide (screw 66 of Harrington) through the retaining member 54 such that the guide can guide the retaining member into position.

It is respectfully submitted that Harrington does not anticipate the apparatus of claim 1 in that each and every element recited in claim 1 is not disclosed by Harrington as required by 35 U.S.C. §102(b). Specifically, claim 1 recites an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of the spinal column. Claim 1 also recites a first mounting member connectable with the first vertebra and the artificial disc and engageable with the artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae. Claim 1 further recites that the first retaining member includes a guide with an outer surface that (a) extends outwardly from the outer surface of the first retaining member and (b) is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae. The Office Action asserts that members 54 and 32 of Harrington correspond to the first retaining member and the first mounting member, respectively, of claim 1. As recognized in the Office Action, however, Harrington does not disclose that member 54 has an outer surface engageable with a vertebra of a spinal column. The Office Action



attempts to overcome this deficiency of Harrington by making the unsupported assertion, as to member 54 of Harrington, that "if one so desired, one could engage the outer surface with a first vertebra." Further, in order to assert that the member 32 of Harrington guides insertion of the artificial disc into position between the first and second vertebrae after the member 32 is connected to the first vertebra, as would be required by claim 1, the Office Action hypothesizes inserting individual pieces of the apparatus of Harrington between two vertebrae and then, presumably, assembling the apparatus. This hypothetical insertion of pieces of the apparatus of Harrington and subsequent in-situ assembly is, however, contrary to the only disclosure in Harrington regarding insertion of the apparatus between two vertebrae, which is set out at column 4, lines 22-27 of Harrington.

Beyond the absence of any disclosure in Harrington to support the foregoing assertions, the Office Action states that the member 32 of Harrington corresponds to the first mounting member of claim 1. According to the Office Action, the member 32 of Harrington is (i) connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. It is respectfully submitted that if the member 32 of Harrington is engageable with the artificial disc to guide movement of the artificial disc into position between the first and second vertebrae, there is no possibility of the member 54 of Harrington engaging a vertebra. Specifically, if the member 54 of Harrington is already engaged with the vertebra, the member 54 cannot be guided into position between the vertebrae by

the member 32 of Harrington. If, on the other hand, the member 32 of Harrington is engageable with the member 54 of Harrington after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae, as would be required by claim 1, the member 32 of Harrington would fully cover the outer surface of the member 54 of Harrington. Thus, there would be no possibility of the outer surface of the member 54 of Harrington being engaged with a vertebra after the artificial disc is in position between the first and second vertebrae.

In addition to the foregoing, the Office Action appears to have identified two different elements of Harrington as corresponding to the guide recited in claim 1 – the threads of hole 55 of Harrington and the screw 66 of Harrington. Applicant is unable to determine whether the Office Action intended to assert that (i) only the threads of the hole 55 of Harrington correspond to the guide of claim 1 or (ii) only the screw 66 of Harrington corresponds to the guide of claim 1 or (iii) the threads of the hole 55 of Harrington and the screw 66 of Harrington together correspond to the guide of claim 1. Applicant is thus unable to address this aspect of the rejection of claims 1, 9-11, 14, and 15 as anticipated by Harrington. In view of the foregoing ambiguity in the Office Action, Applicant respectfully requests withdrawal of this rejection of claims 1, 9-11, 14, and 15 based on Harrington.

Since Harrington does not disclose either (a) an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of a spinal column or (b) a first mounting member engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into

position between the first and second vertebrae, all as recited in claim 1, Harrington cannot anticipate claim 1 under 35 U.S.C. §102(b). Claim 1 is therefore novel and allowable over Harrington.

Claims 9-11, 14, and 15 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the foregoing discussion of claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 9-11, 14, and 15 define over Harrington, and withdrawal of this rejection of claims 9-11, 14, and 15 is respectfully requested.

**5. Rejection of Claims 1, 19, 27, 37, and 38 Under 35 U.S.C. §102(e)**

Claims 1, 19, 27, 37, and 38 have been rejected as anticipated under 35 U.S.C. §102(e) by U.S. Patent No. 7,060,097 to Fraser et al. (hereinafter, "Fraser"). It is respectfully submitted that claim 1 and claims 19, 27, 37, and 38 are novel over Fraser.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Foundation v. Genentech Inc., 1927 F.2d 1565, 8 USPQ2d 1001 (Fed. Cir. 1991).

The Office Action states that Fraser discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Fraser comprises an artificial disc that includes (a) a resilient core

(member 230 of Fraser) having a first surface and a second surface, (b) a first retaining member (member 210 of Fraser), and (c) a second retaining member (member 220 of Fraser). The Office Action also states that the first retaining member of Fraser has an inner surface facing the resilient core and an outer surface “(Fig. 7B inset)” engageable with a first vertebra of the spinal column. Further, according to the Office Action, the second retaining member of Fraser has an inner surface facing the resilient core and an outer surface engageable with a second vertebra of the spinal column. Still further, the Office Action asserts that the apparatus of Fraser also comprises a first mounting member (member 300 of Fraser) that is (i) connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae.

In addition to the foregoing, the Office Action hypothesizes that the first mounting member of Fraser (member 300 of Fraser) could be inserted between two vertebrae prior to engaging the mounting member with the first retaining member (member 210 of Fraser), if one so desired. The Office Action states that the first mounting member (member 300 of Fraser) is (i) connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. Further, according to the Office Action, the first retaining member of Fraser (member 210 of Fraser) includes a guide “(Fig. 7B inset)” with an outer

surface that extends outwardly from the outer surface of the first retaining member and that is engageable with the first retaining member of Fraser to guide movement of the first retaining member into position between first and second vertebrae.

It is respectfully submitted that Fraser does not anticipate the apparatus of claim 1 in that each and every element recited in claim 1 is not disclosed by Fraser as required by 35 U.S.C. §102(b). Specifically, claim 1 recites an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of the spinal column. Claim 1 also recites a first mounting member connectable with the first vertebra and the artificial disc and engageable with the artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae. Claim 1 further recites that the first retaining member includes a guide with an outer surface that (a) extends outwardly from the outer surface of the first retaining member and (b) is engageable with the first mounting member to guide movement of the first retaining member into position between the first and second vertebrae.

The Office Action asserts that members 210 and 300 of Fraser correspond to the first retaining member and the first mounting member, respectively, of claim 1. As recognized in the Office Action, however, Fraser does not disclose that member 300 (the asserted mounting member of Fraser) is engageable (a) with the artificial disc of Fraser after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae or (b) with the asserted guide of member 210 (the retaining member of Fraser) to guide movement of the first retaining member into position between the first and second vertebrae.

The Office Action attempts to overcome this deficiency of Fraser by hypothesizing that “if one so desired”, one could insert the mounting member of the apparatus of Fraser (member 300 of Fraser) between first and second vertebrae before engaging the mounting member with the first retaining member (member 210 of Fraser). This hypothetical insertion and in-situ assembly of the apparatus of Fraser is, however, contrary to the only disclosure in Fraser regarding insertion of the apparatus between two vertebrae, which is set out at column 4, line 51 to column 5, line 22 of Fraser.

Since Fraser does not disclose a first mounting member engageable (a) with an artificial disc after being connected to a first vertebra to guide movement of the artificial disc into position between first and second vertebrae or (b) with a guide of a first retaining member to guide movement of the first retaining member into position between the first and second vertebrae, all as recited in claim 1, Fraser cannot anticipate amended claim 1 under 35 U.S.C. §102(e). Amended claim 1 is therefore novel and allowable over Fraser.

Claims 19, 27, 37, and 38 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the foregoing discussion of claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 19, 27, 37, and 38 define over Fraser, and withdrawal of this rejection of claims 19, 27, 37, and 38 is respectfully requested.

**6. Rejection of Claims 1, 19, 28, and 29 Under 35 U.S.C. §102(e)**

Claims 1, 19, 28, and 29 have been rejected a second time as anticipated under 35 U.S.C. §102(e) by Ross. It is respectfully submitted that claim 1 and claims 9, 28, and 29 are novel over Ross.

Anticipation requires a single prior art reference that discloses each element of the claim. W. L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984). For a reference to anticipate a claim, “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” Scripps Clinic & Research Foundation v. Genentech Inc., 1927 F.2d 1565, 8 USPQ2d 1001 (Fed. Cir. 1991).

This second rejection under 35 U.S.C. §102(e) based on Ross appears to be based specifically on Fig. 5 of Ross, as the Office Action includes an earlier rejection under 35 U.S.C. §102(e) based on Ross that appears to be based specifically on Fig. 3B of Ross. The Office Action states, with particular reference to Fig. 5 of Ross, that Ross discloses an apparatus for replacing a damaged spinal disc in a spinal column. According to the Office Action, the apparatus of Ross comprises an artificial disc that includes (a) a resilient core (member 20 of Ross) having a first surface and a second surface, (b) a first retaining member “(Fig. 5 inset),” and (c) a second retaining member “(Fig. 5 inset).” The Office Action also states that the first retaining member of Ross has an inner surface facing the resilient core and an outer surface engageable with a first vertebra of the spinal column. Further, according to the Office Action, the second retaining member of Ross has an inner surface facing the

resilient core and an outer surface engageable with a second vertebra of the spinal column. Still further, the Office Action asserts that the apparatus of Ross also comprises a first mounting member “(Fig. 5 inset)” that is (i) connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. According to the Office Action, the first retaining member of Ross has a guide “(Fig. 5 inset)” with an outer surface that extends outwardly from the outer surface of the first retaining member to guide movement of the first retaining member into position between first and second vertebrae.

The Office Action appears, based on the repeated references to “Fig. 5 inset”, to be relying on the labeled sketch included at page 16 of the Office Action to identify features corresponding to the outer surface of the first and second retaining members, the mounting member, and the guide of Fraser. From the labeled sketch on page 16 of the Office Action, it appears that the Office Action is asserting that (i) the member 22 and the unnumbered member that is identified as 14 in other Figures together represent the first retaining member of Fig. 5 of Ross, (ii) the member 24 and the unnumbered member that is identified as 16 in other Figures together represent the second retaining member of Fig. 5 of Ross, (iii) the members 38 represent the first and second mounting members of Fig. 5 of Ross, and (iv) the unnumbered member that is identified as 14 in other Figures represents the guide of the first retaining member of Fig. 5 of Ross. Applicant’s response to this rejection based on Ross is premised on the above stated understanding of the intent of the



references to "Fig. 5 inset" and the labels in the sketch on page 16 of the Office Action.

It is respectfully submitted that Ross does not anticipate the apparatus of claim 1 in that each and every element recited in claim 1 is not disclosed by Ross as required by 35 U.S.C. §102(e). Specifically, claim 1 recites an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of the spinal column and a second retaining member having an outer surface engageable with a second vertebra of the spinal column. Claim 1 also recites a first mounting member connectable with the first vertebra and the artificial disc and engageable with the artificial disc after being connected to the first vertebra to guide movement of said artificial disc into position between the first and second vertebrae. Based on the labels in the sketch on page 16 of the Office Action, the Office Action appears to be asserting that the upper surface of member 22 of Fig. 5 of Ross corresponds to the outer surface of the first retaining member of claim 1 and that the lower surface of member 24 of Fig. 5 of Ross corresponds to the outer surface of the second retaining member of claim 1. As recognized in the Office Action, however, Ross does not disclose that either member 22 or member 24 has an outer surface engageable with a vertebra of a spinal column. The Office Action attempts to overcome this deficiency of Ross by making the unsupported assertions, as to members 22 and 24, respectively, of Ross, that "if one so desired, one could engage the outer surface with a first vertebra" and "if one so desired, one could engage the outer surface with a second vertebra." Not only is there no disclosure in Ross of engaging the outer surfaces of members 22 and 24 with vertebrae, the

unnumbered member that is identified as 14 in other Figures of Ross fully covers the outer surface of the member 22 of Ross, and the unnumbered member that is identified as 16 in other Figures of Ross fully covers the outer surface of member 24 of Ross. Thus, there is no possibility of the labeled outer surface of either the member 22 or the member 24 of Ross being engaged with a vertebra if the unnumbered member that is identified as 14 in other Figures of Ross, for example, corresponds to the guide of the first retaining member recited in claim 1, as asserted in the Office Action, and thus is included in the first retaining member of claim 1.

Beyond the absence of any disclosure in Ross to support the foregoing assertions, the Office Action appears to states that the pin 38 of Ross corresponds to the first mounting member of claim 1. According to the Office Action, the pin 38 of Ross is (i) connectable with the first vertebra and the artificial disc to position the artificial disc between the first and second vertebrae and (ii) engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae. It is respectfully submitted that there is no disclosure in Ross of the pin 38 being connectable with a vertebra or being engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc. Specifically, as described in paragraph 044 of Ross, the pins 38 secure the members 14 and 16 of Ross to the members 22 and 24. There is no feature on any pin 38 to permit it to be connected to a vertebra. There is no mention in Ross of connecting any pin 38 to a vertebra and then using the pin to guide movement of a hypothetical structure comprising

members 14, 16, 20, 22, and 24 of Ross. The position taken in the Office Action thus involves a speculative redesign of the apparatus disclosed in Ross.

Since Ross does not disclose either (a) an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of the spinal column and a second retaining member having an outer surface engageable with a second vertebra of the spinal column or (b) a mounting member connectable with the first vertebra and engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae, all as recited in claim 1, Ross cannot anticipate claim 1 under 35 U.S.C. §102(e). Amended claim 1 is therefore novel and allowable over Ross.

Claims 19, 28, and 29 depend, directly or indirectly, from claim 1 and are allowable for at least the reasons given in the foregoing discussion of claim 1 and further for the recitations contained in those claims. It is thus respectfully submitted that claims 19, 28, and 29 define over Ross, and withdrawal of this rejection of claims 19, 28, and 29 is respectfully requested.

**7. Rejection of Claims 5, 6, 23, 24, 31, 39 and 40 Under 35 U.S.C. §103(a)**

Claims 5, 6, 23, 24, 31, 39 and 40 have been rejected as unpatentable under 35 U.S.C. §103(a) over Ross (Fig. 3B). It is respectfully submitted that claims 5, 6, 23, 24, 31, 39 and 40 define over the cited art.

Each of claims 5, 6, 23, 24, 31, 39 and 40 depends, directly or indirectly, from claim 1. The Office Action appears to be premising the rejection of claims 5, 6, 23, 24, 31, 39 and 40 on the rejection of claim 1 and dependent claims 19 and 30 as

anticipated under 35 U.S.C. §102(e) by Fig. 3B of Ross. As previously discussed, however, Fig. 3B of Ross does not disclose an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of the spinal column and a second retaining member having an outer surface engageable with a second vertebra of the spinal column, as recited in claim 1. Consequently, claim 1 is not anticipated by Ross under 35 U.S.C. §102(e). Further, the claim 1 is neither suggested nor taught by Ross and is allowable over Ross. As claims 5, 6, 23, 24, 31, 39 and 40 depend, directly or indirectly, from amended claim 1, claims 5, 6, 23, 24, 31, 39 and 40 are allowable for at least the reasons given in the discussion of claim 1 in connection with its rejection as anticipated under 35 U.S.C. §102(e) by Fig. 3B of Ross and further for the recitations contained in those claims. It is thus respectfully submitted that claims 5, 6, 23, 24, 31, 39 and 40 define over the cited art, and withdrawal of this rejection of claims 5, 6, 23, 24, 31, 39 and 40 is respectfully requested.

**8. Rejection of Claims 35 and 36 Under 35 U.S.C. §103(a)**

Claims 35 and 36 have been rejected as unpatentable under 35 U.S.C. §103(a) over Harrington in view of U.S. Patent No. 5,370,697 to Baumgartner (hereinafter, "Baumgartner"). It is respectfully submitted that claims 35 and 36 define over the cited art.

Claims 35 and 36 depend, directly or indirectly, from claim 1. The Office Action appears to be premising the rejection of claims 35 and 36 on the rejection of claim 1 as anticipated under 35 U.S.C. §102(b) by Harrington. As previously discussed, however, Harrington does not disclose either (a) an artificial disc that

includes a first retaining member having an outer surface engageable with a first vertebra of a spinal column or (b) a first mounting member engageable with the artificial disc after being connected to the first vertebra to guide movement of the artificial disc into position between the first and second vertebrae, all as recited in claim 1. Consequently, claim 1 is not anticipated by Harrington under 35 U.S.C. §102(b). Claim 1 is also neither suggested nor taught by Harrington and is allowable over Harrington. Further, Baumgartner does not overcome the deficiencies of Harrington with respect to claim 1 because Baumgartner does not disclose an artificial disc that includes a first retaining member having an outer surface engageable with a first vertebra of a spinal column, as recited in claim 1. Claim 1 is therefore allowable over both Harrington and Baumgartner. As claims 35 and 36 depend, directly or indirectly, from amended claim 1, claims 35 and 36 are allowable for at least the reasons given in the discussion of claim 1 in connection with its rejection as anticipated under 35 U.S.C. §102(b) by Harrington and further for the recitations contained in those claims. It is thus respectfully submitted that claims 35 and 36 define over the cited art, and withdrawal of this rejection of claims 35 and 36 is respectfully requested.

**II. Conclusion**

In view of the foregoing amendment and remarks, it is respectfully submitted that claims 1 and 4-47 define over the cited art. Withdrawal of the rejections of the claims and the passage of the application to issue is therefore requested.

Please charge any deficiency or credit any overpayment in the fees for this matter to our Deposit Account No. 20-0090.

Respectfully submitted,

/James L. Tarolli/

James L. Tarolli  
Reg. No. 36,029

TAROLLI, SUNDHEIM, COVELL,  
& TUMMINO L.L.P.  
1300 East Ninth Street, Suite 1700  
Cleveland, Ohio 44114  
Phone: (216) 621-2234  
Fax: (216) 621-4072  
Customer No.: 26,294